



PATENT  
Docket No. 377882000900

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Gary VAN NEST

Serial No.: 09/802,686

Filing Date: March 9, 2001

For: METHODS OF PREVENTING AND  
TREATING RESPIRATORY VIRAL  
INFECTION USING  
IMMUNOMODULATORY  
POLYNUCLEOTIDE SEQUENCES

Examiner: R. A. Schnizer

Group Art Unit: 1635

DECLARATION OF GARY VAN NEST, PH.D.  
PURSUANT TO 37 C.F.R. § 1.132

Box RCE  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, Gary Van Nest, Ph.D., declare as follows:

1. I currently reside at 639 Skyline Drive, Martinez, California 94553.
2. I am the inventor named in the above-referenced patent application, and am familiar with the patent specification.
3. Described herein are results from an experiment performed by me or under my direction on respiratory syncytial virus (RSV) infection. This experiment was carried out as described in Examples 1 and 2 of the patent specification using cotton rats, RSV strain A2 and

oligonucleotides SEQ ID NO:1 and SEQ ID NO:9, as described on page 38 of the patent specification.

4. Twenty cotton rats were divided into 5 groups of four animals and treated once intranasally with varying doses of an ISS-containing oligonucleotide (SEQ ID NO:1) or with controls. Three days later, each animal was inoculated intranasally with 100 median tissue culture infectious doses (TCID<sub>50</sub>) of RSV A2. Four days after viral inoculation, each animal was sacrificed. The lungs were removed, rinsed, and viral titers determined using virus-induced cytopathic effects as an endpoint as described in Example 1 on pages 38 and 39 of the patent specification.

5. The results of this experiment are herein presented in Table 1 and Figure 1 in Exhibit A. Cotton rats, treated once intranasally with a 150 µg dose of the ISS-containing oligonucleotide, showed a reduction in RSV virus lung titers in 3 of 4 animals compared to animals treated with PBS (see Exhibit B). Rats treated with either the 50 or 450 µg dose of the ISS-containing oligonucleotide or with non-ISS oligonucleotide (SEQ ID NO:9) showed no significant reduction in viral titers following RSV infection.

6. The data indicates that administration of 150 µg of an ISS-containing oligonucleotide to the site of RSV exposure results in a statistically significant reduction in lung viral titers compared to PBS treated animals.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

January 7, 2003

Date

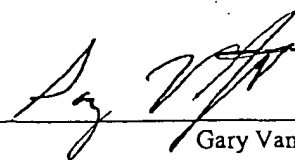
  
\_\_\_\_\_  
Gary Van Nest



Exhibit A.

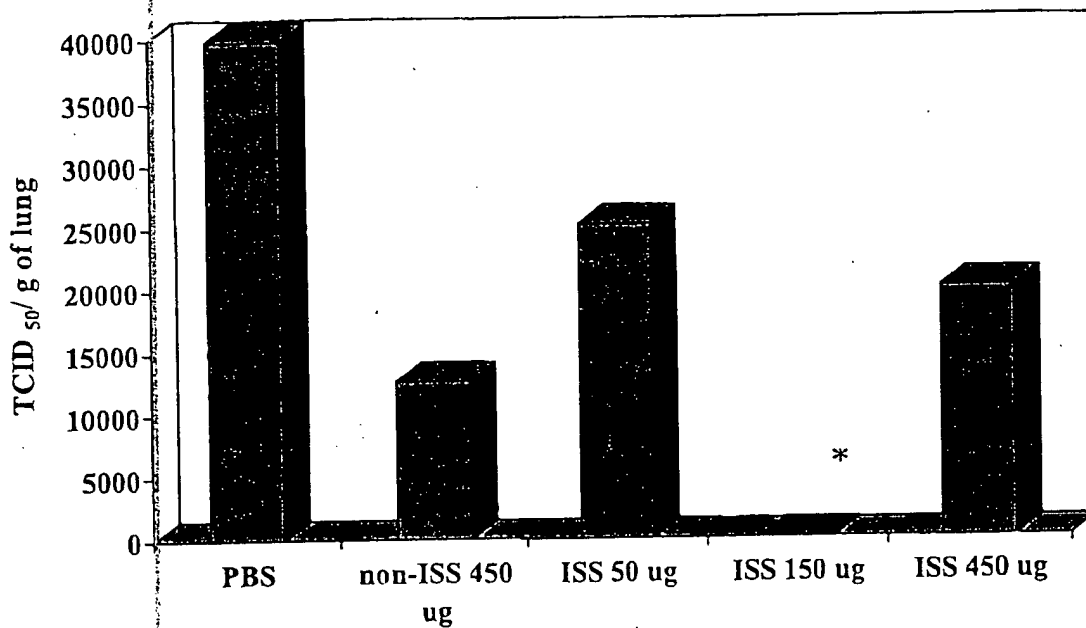
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Table 1. RSV titers in lung

Group	Treatment	TCID <sub>50</sub> (log <sub>10</sub> /g lung) in cotton rat no.				Mean	Std. Dev.
		1	2	3	4		
1	PBS	4.5	5	4	5	4.6	0.5
2	Non-ISS, 450 ug	4	4	4	4.5	4.1	0.3
3	ISS, 50 ug	5	4.5	4	4	4.4	0.5
4	ISS, 150 ug	3	4	0	0	1.8*	2.1
5	ISS, 450 ug	4	4	4.5	4.5	4.3	0.3

\* p=0.05 compared to PBS, Kruskal-Wallis, nonparametric test

Figure 1.



\* p=0.05 compared to PBS, Kruskal-Wallis, nonparametric test